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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/534,995 | 03/27/2000 | Satoru Nishimura | 0213-1431-0 | 4205 |

7590 01/24/2003

OBLON SPIVAK MCCLELLAND MAIER & NEUSTADT
Fourth Floor
1755 Jefferson Davis Highway
Arlington, VA 22202

[REDACTED] EXAMINER

EPPS, JANET L

[REDACTED] ART UNIT

[REDACTED] PAPER NUMBER

1635

DATE MAILED: 01/24/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/534,995 | NISHIMURA ET AL. | |
| | Examiner | Art Unit | |
| | Janet L Epps-Ford, Ph.D. | 1635 | |

-- The MAILING DATE of this communication app ears on the cover she et with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 12 November 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 2-6,8-17 and 23-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 2 and 8 is/are allowed.
- 6) Claim(s) 3-6,9-12,14-17 and 23-44 is/are rejected.
- 7) Claim(s) 13 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. **Corrections other than Informalities Noted by Draftsperson on form PTO-948.** All changes to the drawings, other than informalities noted by the Draftsperson, MUST be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings MUST be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

2. Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.85(a). Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Amendment

4. In response to the objection of Claims 14-17 under 37 CFR 1.75(c), and the objection of claim 13 set forth in the prior Office Action, Applicants state (page 5, last two paragraphs) that the objection of claims 13-17 are obviated by amendment. However, contrary to Applicant's assertions there is no record of any amendment to claims 13-17.

Response to Arguments

5. Claims 3-6, 9-12, 14-17 and claims 23-44 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

application was filed, had possession of the claimed invention, for the reasons of record set forth in the Official Action mailed 8-09-2002.

Applicant's arguments filed 11-12-2002 have been fully considered but they are not persuasive. Applicants traverse the instant rejection on the grounds that the present claims are directed to specific DNA sequences; or DNA sequences which hybridize to those DNA under stringent conditions, which have 90% homology with the nucleotide sequences, and which encode a protein or a peptide with activity. Additionally, Applicants direct the examiner's attention to Example 9 of the "Synopsis of Application of Written Description Guidelines," and to pages 8-9 of the specification as filed which describes the stringent conditions in the present claims.

It is first noted that the conditions of hybridization set forth on pages 8-9 of the specification as filed are not recited in the instant claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Moreover, the hybridization conditions set forth on pages 8-9 of the specification as filed would allow hybrids having 60% homology or more, preferably 80% homology or more to the target gene. However, Applicants have not clearly set forth those conditions that would produce specific hybrids to the target sequence having 90% homology. Moreover, there is no specific guidance, aside from the need for further experimentation, which would allow the skilled artisan to predict the DNA sequences of those DNA hybrids having 90% homology to the target sequences and furthermore encodes a protein having choline monooxygenase activity.

It is apparent that Applicants have not clearly set forth the chemical structures of the genus of compounds encompassed by the claimed invention. More experimentation is required for the skilled artisan to identify the full scope of compounds encompassed by the claimed invention. Therefore, the full scope of the claimed invention was not “ready for patenting” at the time of filing of the instant application. As per the January 5, 2001 (Vol. 66, No. 4, pages 1099-1111) Federal Register for the Guidelines for Examination of Patent Applications Under the 35 USC 112 ¶ 1, “Written Description” Requirement: “[T]o satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was “ready for patenting” such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that applicant was in possession of the claimed invention.” Possession cannot be established by describing a means for isolating a structure; the invention must be described by descriptive means such as by words, structures, figures, diagrams, etc. Applicants seek to describe the claimed invention by describing a means to isolate the genus of DNA molecules encompassed by the claimed invention.

As stated in the prior Office Action, the specification as filed provides sufficient guidance with regards to the isolation, characterization, and use of genes encoding proteins according to

SEQ ID NO: 2, 4, 6, or 17 wherein said proteins have choline monooxygenase activity or signal peptide activity, wherein said genes have a sequence according to SEQ ID NO: 1, 3, 5, or 16 respectively. However, the specification as filed does not provide a specific structural description of the full scope of nucleotide sequences encompassed by the claimed invention, particularly wherein the nucleic acid sequence hybridizes under stringent conditions, *i.e.* DNAs having 90% homology or more to the sequences according to SEQ ID NO: 1, 3, 5, or 16, and still encode a protein that maintains either signal peptide activity or CMO activity. Moreover, the specification as filed does not provide sufficient guidance and/or instruction that would unambiguously direct one of skill in the art to design the full scope of gene sequences encompassed by the claimed invention.

Applicants have not provided a sufficient written description that would clearly indicate that Applicants were in possession of the full scope of the claimed invention at the time of filing of the instant Application.

Claim Objections

6. Claims 14-17 remain objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim may not serve as a basis for any other multiple dependent claim, either directly or indirectly. See MPEP § 608.01(n).

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: 1635

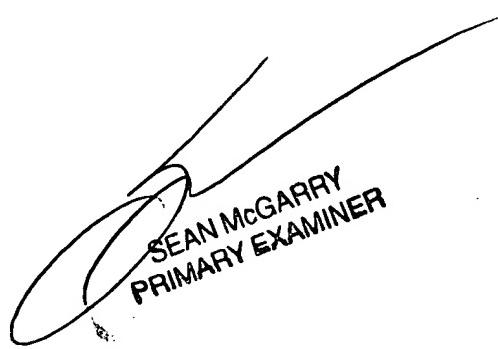
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L Epps-Ford, Ph.D. whose telephone number is 703-308-8883. The examiner can normally be reached on M-T, Thurs-Friday 9:00AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703)-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-746-5143 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Janet L Epps-Ford, Ph.D.
Examiner
Art Unit 1635

JLE
January 21, 2003



A handwritten signature in black ink, appearing to read "JLE". Below it is a stylized, cursive signature that includes the name "SEAN McGARRY" and the title "PRIMARY EXAMINER" written in a bold, slanted font.